Amendment and response to Office Action dated March 7, 2007 (Amendment C)

REMARKS

Claim 21–38 are pending in the present application following amendment as proposed herein.

Claim 21, from which all other claims directly or indirectly depend, is amended for greater clarity as follows.

- The process step previously described as "causing an adult subject ... to use ... a kit ..." is now defined by reciting two process steps: a first step of "providing to an adult subject ... a kit" and a second step of "encouraging and/or assisting the subject to arrange separate pieces from the kit ...". The two-step method of "providing" and "encouraging and/or assisting" finds support in the specification as filed at least at page 2, line 26 – page 3, line 1.
- The word "separate" is inserted before "pieces" to provide further clarity to the definition of a "kit" as comprising pieces that, as provided to the subject, are separate, i.e., not already connected to one another. The specification at page 2, line 26 distinguishes a "kit" from other types of "article" by noting that a kit comprises separate pieces.
- Recitation of the property of the pieces as being "suitable for arrangement by the subject" is replaced by the clearer recitation of the "encouraging and/or assisting" process step.

Claim 21 is further amended to be drawn to an embodiment of the invention wherein the pieces are "soft on all sides". This amendment finds support in the specification as filed at least at page 6, lines 12–15, where it is noted that an activity aid having pieces that are soft on all sides is "preferred" as posing minimal risk of injury to the subject or to others in the vicinity.

Each of dependent Claims 22-38 is amended to conform, for example in antecedent basis, to Claim 21 as amended herein.

Claim 24 is further amended to replace the term "VelcroTM" with the term "hook and loop fastening strips", which is a dictionary definition of a product whose trademark is well known and understood by those of skill in the art. This amendment is made in the interest of avoiding use of a trademark in the present claims, so as to further enhance clarity.

No new matter is introduced by any amendment proposed herein, and no change in inventorship results therefrom.

RESPONSE TO OFFICE ACTION DATED MARCH 7, 2007

1. Terminal disclaimer

In Applicant's response dated July 3, 2006, confirmation was requested in the next communication from the Office that Applicant presently stands \$65 in credit with respect to this application, in view of double payment of a fee for filing a terminal disclaimer. This request has not been considered in the present Action, thus the Office's confirmation is once again respectfully requested that Applicant presently stands \$65 in credit with respect to this application.

2. Rejection under 35 U.S.C. §112, second paragraph

Claims 21–28 and 30–38 stand rejected under 35 U.S.C. §112, second paragraph as being allegedly indefinite for reciting a use without any active, positive steps delimiting how this use is actually practiced.

This rejection is respectfully traversed, it being clear from a reading of the specification as a whole what is meant by "use as an activity aid". However, the rejection is moot in view of the amendment proposed herein, by which the single "causing to use" process step is replaced by a "providing" step and an "encouraging and/or assisting" step, which will be seen to be active, positive steps delimiting how the use is practiced.

Claim 24 stands rejected under 35 U.S.C. §112, second paragraph as being allegedly indefinite for reciting the trademark VelcroTM.

This rejection is respectfully traversed. Notwithstanding the Board's finding in Ex parte Simpson, 218 USPQ 1020, cited by the Examiner, the trademark VelcroTM is among a small group of trademarks that are so universally familiar as to immediately identify the product or material intended, thus its use in Claim 24 does not render the claim indefinite. The Examiner's attention is respectfully drawn to Claim 7 of U.S. Patent No. 4,205,850 to

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Craig, cited in the present Action, which recites "VELCRO" yet was found allowable by the Office.

However, the rejection is moot in view of the amendment proposed herein, by which the term "VelcroTM" is replaced by the term "hook and loop fastening strips". This descriptive term constitutes an ordinary dictionary definition of "Velcro" and therefore does not add new matter. See, for example, <u>Encarta World English Dictionary</u>, which defines Velcro as "a trademark for a fastener consisting of two strips, one with a dense layer of hooks and the other of loops, used especially on outerwear, athletic shoes and luggage."

Withdrawal of the present claim rejections under 35 U.S.C. §112, second paragraph is respectfully requested.

3. Rejection under 35 U.S.C. §101

Claims 21–38 stand rejected under 35 U.S.C. §101 as being directed to non-statutory subject matter for allegedly failing to produce a useful, tangible and concrete result. This rejection is respectfully traversed.

The Examiner alleges the claims fail to produce a concrete result, offering in support of this position that a therapeutically beneficial cognitive challenge appropriate to the subject's mental acuity "cannot be guaranteed in every case due to the large variation of human mental characteristics", and that "[t]here is no guarantee that the claimed result will occur with each individual user of the system", citing MPEP 2106. See Action, [4], lines 6–8 (emphasis added).

Applicant makes the following submission in rebuttal of the Examiner's position.

- The cited section of MPEP relates specifically to computer-related inventions, under which the present invention cannot conceivably be classified. Statements therein relating to what constitutes a statutorily patentable process, for example, the statement (MPEP 2106.IV.2(b)(ii)) that "[a] claim is limited to a practical application [and therefore statutory] when the method, as claimed, produces a concrete, tangible and useful result", citing AT&T v. Excel Communications, 172 F.3d 1352, are clearly limited in their applicability to computer-related inventions.
- The Examiner's attention is respectfully drawn to a much more pertinent section of

MPEP, relating to "Therapeutic or Pharmacological Utility" (MPEP 2107.01.III). In particular, this section, citing *In re Gazave*, 379 F.2d 973, states: "...in the usual case where the mode of operation alleged can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned, and no further evidence is required" (emphasis added). MPEP goes on to state that "pharmacological or therapeutic inventions that provide any 'immediate benefit to the public' satisfy 35 U.S.C. 101" (emphasis in original). The same section, in relation to process claims, states that "[i]f the asserted utility is credible, there is no basis to challenge such a claim on the basis that it lacks utility under 35 U.S.C. 101" (emphasis in original). Applicant submits that there is nothing incredible about the utility asserted for the present invention, namely a therapeutically beneficial cognitive challenge appropriate to the subject's mental acuity.

- The Office has historically found acuity-appropriate cognitive challenge or stimulation to be a credible utility. See, for example, U.S. Patent No. 5,538,432 to Dondero *et al.*, cited in the present Action. Applicant sees no reason to treat the present invention any differently.
- Guarantee of a positive result "in every case" and "with each individual user" is
 not a proper requirement for utility under 35 U.S.C. §101. With such a
 requirement, the Examiner is attempting to set a standard that would be met by no
 known therapeutic method in any field of medical, psychiatric or geriatric care.

The Examiner has clearly failed to establish a *prima facie* showing of lack of utility and to provide a sufficient evidentiary basis for factual assumptions relied upon, as required by MPEP 2107.02.IV. Withdrawal of the present rejection is respectfully requested.

4. Rejection under 35 U.S.C. §103(a) over Cohen in view of Dondero.

Claims 21–23, 26–29 and 32–38 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Cohen *et al.* (U.S. Patent No. 3,726,027) in view of Dondero *et al.* (U.S. Patent No. 5,082,446). This rejection is respectfully traversed.

It is well established that a *prima facie* case of obviousness requires that <u>all three</u> of the criteria set forth in MPEP §2143 be met. A *prima facie* case of obviousness cannot be

sustained in the present situation, for failure to satisfy at least two of the three criteria, as more fully described below.

4.1. No suggestion or motivation to combine reference teachings

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. MPEP §2143.01.

The Examiner argues that it would have been obvious to incorporate the teachings of Dondero, regarding the therapeutic value of Dondero's device to adults with dementia, into the method of Cohen, which is stated to be of use in teaching word associations and the like to beginning grade school students. In making this argument, the Examiner ignores the file record of the present application in which the art is shown to teach away from use of infant-directed toys and teaching aids for providing cognitive benefit to adult sufferers from dementia.

For example, as pointed out in Applicant's response dated July 3, 2006, U.S. Patent No. 5,082,446 to Sclan & Reisberg states that "[i]nfants are <u>fundamentally different</u> from patients with dementia" (Sclan, column 3, lines 4–5, emphasis added); that "[a]mong the differences are cognitive, motor and behavioral differences" (Sclan, column 3, lines 8–9); and that these differences "render the unmodified use of infant tests for dementia patients uninterpretable, misleading or, in some instances, impossible to administer" (Sclan, column 3, lines 21–24). Thus, Sclan would have led one of skill in the art to conclude that an apparatus useful as a teaching aid for infants (such as the apparatus of Cohen) would be unlikely to have benefit for an adult dementia sufferer. In other words, Sclan <u>teaches away</u> from the combination of Cohen with Dondero.

4.2. All claim limitations not taught or suggested

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. MPEP §2143.03.

Among features recited in Claim 21 that are neither taught nor suggested by Cohen,

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Dondero or a combination thereof (assuming *arguendo* that motivation exists for such combination, which is not admitted herein) are providing to the subject a kit that comprises a plurality of <u>separate</u> pieces that can be arranged by the subject in a simple assembly or construction pastime, puzzle or game. The word "separate", previously implicit in the definition of "kit", is now, following amendment herein, explicitly recited in the claim.

In Dondero, the subject is presented with a variety of sensory elements on a surface; these sensory elements can be manipulated but are fixed and integral to the surface, thus the sensory elements of Dondero are neither "separate" (i.e., unconnected to each other) nor capable of being "arranged" by the subject.

In Cohen, the article provided to the subject is either a fully assembled polyhedron or a flat-form pattern which the subject can use to construct the polyhedron. Contrary to the Examiner's assertion (Action, [20]), construction from flat-form does not involve arrangement of separate pieces. As Cohen's Fig. 1 clearly shows, the flat-form pattern already contains all the faces necessary to form the polyhedron, and these faces are already fastened together with adhesive tape. Thus the faces of the polyhedron presented to the subject are not "separate" as required by the present claims.

Thus, even without the requirement, added by the present amendment, that the pieces be "soft on all sides", Cohen in view of Dondero, even if motivation could be found to combine these references, would not lead one of ordinary skill in the art to the present invention, as not all claim limitations are taught or suggested by a combination of the references.

When separate pieces are provided to an adult dementia sufferer, particularly in a communal setting such as a nursing home or a geriatric or psychiatric hospital, the present inventors conceived that it would be preferable for such pieces to be soft on all sides to minimize risk of injury to the subject or others nearby. Specification, page 6, lines 12–15. This is a consideration that does not apply to Dondero's device, which does not have separate pieces; thus Dondero's device consists of parts, including the sensory elements, that are described therein as "rigid". Dondero, column 2, lines 59 and 65; column 3, line 4. Cohen's polyhedron is constructed from cardboard, plastic or wood veneer (not soft materials);

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individual faces of Cohen's polyhedron (which in any case are not "separate pieces", as pointed out above) can have "pile material" such as felt on one, but not both, sides.

Therefore with the added recitation herein of pieces that are soft on all sides, the combined disclosure of Cohen and Dondero (if such combination were proper) falls even further short of the requirement for prima facie obviousness that all claim limitations must be taught or suggested.

4.3. Dependent claims are not *prima facie* obvious

Each of Claims 22, 23, 26-29 and 32-38 depends from Claim 21. As Claim 21 is believed to be non-obvious over Cohen in view of Dondero for reasons set forth above, all claims dependent therefrom are likewise non-obvious over the cited references. If an independent claim is non-obvious under 35 U.S.C. §103, then any claim depending therefrom is non-obvious. MPEP §2143.03.

For at least the reasons set forth above, Applicant respectfully submits that a prima facie case of obviousness has not been made, and requests withdrawal of the present rejection under 35 U.S.C. §103(a).

5. Rejection under 35 U.S.C. §103(a) over Cohen in view of Dondero and Craig

Claim 24 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Cohen in view of Dondero and in further view of Craig (U.S. Patent No. 4,205,850). This rejection is respectfully traversed.

Claim 24 depends from Claim 23, which as shown above is non-obvious over Cohen in view of Dondero. Craig fails to supply at least one element of Claim 23 that is missing from Cohen and Dondero, namely pieces that are soft on all sides. The playing pieces of the Craig game are not described as being soft on all sides; indeed from the figures in Craig it seems clear that the pieces are of similar hard construction to the board on which the game is said to be played.

Thus at least the requirement for prima facie obviousness that all claim limitations must be taught or suggested is not met by the combination of Cohen, Dondero and Craig. Withdrawal of the present rejection under 35 U.S.C. §103(a) is respectfully requested.

6. Rejection under 35 U.S.C. §103(a) over Cohen in view of Dondero and Lowenstein

Claim 25 stands rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Cohen in view of Dondero and in further view of Lowenstein (U.S. Patent No. 2,076,956). This rejection is respectfully traversed.

Claim 25 depends from Claim 23, which as shown above is non-obvious over Cohen in view of Dondero. Lowenstein fails to supply at least one element of Claim 23 that is missing from Cohen and Dondero, namely pieces that are soft on all sides. The elements of the Lowenstein device are described as "substantially rigid" (column 1, lines 9–10, line 19) and, while they can be formed of "fabric" (column 2, line 17), such fabric is not a "soft fabric" as specified in the present claims but instead is "semi-rigid or rigid" (column 2, lines 15–16).

Thus at least the requirement for *prima facie* obviousness that all claim limitations must be taught or suggested is not met by the combination of Cohen, Dondero and Lowenstein. Withdrawal of the present rejection under 35 U.S.C. §103(a) is respectfully requested.

7. Rejection under 35 U.S.C. §103(a) over Cohen in view of Dondero and Castanis

Claims 30 and 31 stand rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Cohen in view of Dondero and in further view of Castanis (U.S. Patent No. 3,833,222). This rejection is respectfully traversed.

Claims 30 and 31 depend from Claim 26, which as shown above is non-obvious over Cohen in view of Dondero. Castanis fails to supply at least one element of Claim 26 that is missing from Cohen and Dondero, namely pieces that are soft on all sides. The playing pieces of Castanis are described as "simulating dominoes, formed from any suitable material, preferably a plastic" (column 2, lines 55–57) and are clearly not soft on all sides.

Thus at least the requirement for *prima facie* obviousness that all claim limitations must be taught or suggested is not met by the combination of Cohen, Dondero and Castanis. Withdrawal of the present rejection under 35 U.S.C. §103(a) is respectfully requested.

8. Conclusion

Applicant believes the present response to be fully responsive, all grounds of rejection

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being overcome or rendered moot. The application is believed to be in condition for allowance of all pending claims.

Respectfully submitted,

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